Title: COMPOUNDS AND METHODS TO ENHANCE FAAV TRANSDUCTION

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## Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 1 and 87 are amended, and claim 88-89 are added. The amendments are intended to further prosecution and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in an application related to the present application. Claims 1-12, 29-84 and 86-89 are now pending in this application.

Support for the amendment to claims 1 and 87 to recite "enhances transport to the nucleus" and for new claims 88-89 is found, for instance, at page 4, lines 19-31 and Example 5 of the specification.

The Examiner is thanked for the courtesies extended to Applicant's Representatives in the telephonic interview conducted on September 1, 2004. The Interview Summary dated September 28, 2004 reflects the general nature of the interview. However, Applicant's Representatives pointed out that a § 102 "inherency" rejection over Ferrari et al. <u>J. Virol.</u>, 70:3234 (1996) was not appropriate and the Examiner agreed.

## The 35 U.S.C. § 112 Rejections

The Examiner rejected claims 1-12, 29-36, 83-84, and 86 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner also rejected claims 1-12, 29-36, 83-84, and 86 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. These rejections are respectfully traversed.

It is Applicant's position that claim 1 is definite and supported by the specification: it is directed to a method which identifies an agent that enhances adeno-associated virus (AAV) transduction of a mammalian cell after viral binding to the cell membrane and before second strand synthesis which yields an expressible form of the viral genome, wherein the agent enhances transport of the virus to the nucleus (see page 4, lines 19-31 and Example 5).

Accordingly, withdrawal of the § 112 rejections is appropriate and respectfully requested.

## The 35 U.S.C. § 102 Rejection

The Examiner rejected claims 1, 4-5, 10, 12, and 87 under 35 U.S.C. § 102(b) as being anticipated by Ferrari et al., J. Virol., 70:3234 (1996). This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

In particular, the Examiner asserts that Ferrari et al. teach identifying whether an agent alters transduction at the point of uncoating and so concludes that identifying a compound having the claimed activity is inherent to the method of Ferrari et al.

In fact, the disclosed agent which enhanced AAV transduction in Ferrari et al., a plasmid encoding adenovirus (Ad) E4 ORF6, enhanced the conversion of single-stranded to doublestranded AAV DNA, an effect also induced by UV light (pages 3231-3232). And although Ferrari et al. purportedly tested that plasmid for its effect on AAV uncoating (page 3231), Ferrari et al. measured levels of nuclease resistant virion DNA (Figure 5), not necessarily viral uncoating. Further, Ferrari et al. do not teach identifying an agent that enhances viral transport to the nucleus.

Therefore, Ferrari et al. do not anticipate Applicant's invention.

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## **Conclusion**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 44 day of October, 2004.

CANDIS BUENDING

Name

Signature